REMARKS:

In the Office Action dated August 31, 2009, claims 20-25 in the above-identified U.S. patent application were rejected. Reconsideration of the rejections is respectfully requested in view of the above amendments and the following remarks. Claims 20-25 remain in this application, claims 1-13 have been withdrawn, claims 14-19 have been canceled, and new claims 26 and 27 have been added to the application. Support for new claim 26 can be found throughout the application and at least on page 5, lines 33-39 of the present application. Claim 27 is supported throughout the application and at least by the disclosure on page 2, lines 5-11.

Claims 20-25 were rejected under 35 USC §112, first paragraph, as lacking an adequate written description. Claim 20 has been amended to recite specific melatonin derivatives as recited in original claim 2 and on page 2 of the present application. In view of this amendment, applicants request that this rejection be withdrawn.

Claims 20-25 were rejected under 35 USC §103(a) as unpatentable over Pierpaoli in view of Matsumoto further in view of Hanada. Pierpaoli (US 4,746,674) provides a method for treating the skin and/or scalp of a human subject, comprising topically administering an effective amount of a composition comprising melatonin, wherein melatonin is preferably provided in a concentration ranging from 10^{-4} to about 1% by weight. If the composition is orally administered, it is administered at an effective daily dose of about 0.1 to about 100 mg/kg. Matsumoto (US 5,637,606) discloses a composition used as a hair grower, for preventing hair loss, for promoting hair development and for treating alopecia. Matsumoto's composition comprises allantoin or a derivative thereof in combination with at least one aluminium compound. According to

column 1, line 53 to column 2, line 6 of Matsumoto, reagents such as gingko leaf extract have been used in the past. Hanada (US 5,656,264) describes a composition for treating alopecia (e.g. male alopecia or alopecia areata) Hanada's composition comprises at least one compound selected from the group consisting of purine compounds, pyridylurea compounds, diphenylurea compounds, pyrimidine compounds, imidazole compounds, benzoylaminourea compounds and 4-substituted aminopyrrolo[2,3-d]pyrimidine compounds. The composition may contain at least one additional compound commonly used for promoting hair growth such as biotin (cf. column 13, lines 15-38), to activate enzymes of hair-matrix cells to promote synthesis of hair (cf. column 1, lines 33-38).

Applicants respectfully contend that this rejection is based on inadmissible hindsight. One skilled in the art would not have been motivated to employ gingko biloba in Pierpaoli's composition based on the disclosure of Matsumoto. Though Matsumoto generally mentions the use of gingko extracts for promoting hair growth in the text passage relating to the discussion of the prior art, Matsumoto does not disclose gingko biloba as an essential component of the composition nor does Matsumoto disclose a working example employing a composition comprising gingko biloba. Thus, one skilled in the art is not clearly directed to a composition comprising both melatonin and gingko biloba. In addition, Matsumoto teaches that conventional hair growers containing pharmaceutically effective components (e.g. gingko leaf extract) have not been able to achieve satisfactory effects in the prevention and inhibition of dandruff, itching and hair falling, as well as in promotion of hair development and growth (cf. column 2, lines 14-21). Thus, Matsumoto actually teaches away from using gingko biloba as an active

ingredient in compositions for promoting hair growth. Hanada does not specifically teach the use of biotin as an active ingredient in a composition for promoting hair growth either. Hanada teaches biotin as one of numerous compounds which are optionally employed in his composition. Hanada lists numerous compounds in col. 1, lines 16-47 (including biotin) which he indicates are ineffective as used in the prior art. Applicants point out that none of the working examples teaches a composition comprising biotin. Thus, the skilled person would not have been motivated to specifically select biotin as a mandatory component of a composition for promoting hair growth based on the teaching of Hanada. At best, applicants contend that it would only have been obvious to try various compounds disclosed in Hanada with Pierpaoli's melatonin. Applicants point out column 1, lines 42-47 of Hanada which indicates that conventional ingredients such as biotin have proven to exhibit a hair growth-promoting effect or an alopecia-preventing effect to some extent. However, those conventional ingredients are described as having failed to give a satisfactory result in promoting hair growth and curing alopecia, such that one of ordinary skill in the art would not have considered using biotin as an active ingredient in compositions for promoting hair growth in the absence of Hanada's active ingredients (i.e. purine compounds, pyridylurea compounds, diphenylurea compounds, pyrimidine compounds, imidazole compounds, benzoylaminourea compounds and 4-substituted aminopyrrolo[2,3-d]pyrimidine compounds). Thus, Matsumoto and Hanada discuss ginko and biotin as prior art compounds and indicate that they are generally ineffective unless combined with particular active ingredients. Since the combination of cited prior art does not suggest or disclose a method for promoting hair growth on a subject in need of such promotion

comprising applying to areas of the subject where hair growth is desired, a composition comprising as active ingredients (a) melatonin or a derivative thereof selected from the group consisting of 5-methoxytryptamine, 5-methoxytryptophan, 5-methoxytryptophol, 5-methoxyindole-3-acetic acid and 6-hydroxymelatonin, and physiologically acceptable salts, esters and complex compounds thereof, (b) ginko biloba and (c) biotin, applicants request that this rejection be withdrawn.

Enclosed with this response is a non-comparative, multi-center clinical study on the efficacy and safety the commercial product Asatex® (MEL-COS-AS05). This study includes 1900 male and female patients aged between 18 and 40 years. In the study, Asatex® was topically administered over a period of 90 days, showing the claimed combination of melatonin, biotin and gingko biloba to be both well tolerable and effective in the treatment of patients affected by early stages of androgenic alopecia by generating a protective effect against oxidative stress, stimulating the hair follicles and inducing revitalization of the hair. Applicants point out that Matsumoto and Hanada teach away from the present invention by indicating that biotin and ginko biloba are ineffective for promoting hair growth in the absence of active ingredients such as allantoin, purine compounds, pyridylurea compounds, diphenylurea compounds, pyrimidine compounds, imidazole compounds, benzoylaminourea compounds and 4-substituted aminopyrrolo[2,3-d]pyrimidine compounds. The above discussed results surprisingly show that melatonin can be combined with biotin and ginko biloba to effectively promote hair growth when used in the present invention.

Applicants respectfully submit that all of claims 20-27 are now in condition for allowance. If it is believed that the application is not in condition for allowance, it is

respectfully requested that the undersigned attorney be contacted at the telephone number below.

In the event that this paper is not considered to be timely filed, the Applicant respectfully petitions for an appropriate extension of time. Any fee for such an extension together with additional fees that may be due with respect to this paper, may be charged to Counsel's Deposit Account No. 02-2135.

Respectfully submitted,

By 

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MCK/cb

ASATONA AG

Use Test

Open-label, non comparative, multi-center clinical study on efficacy and safety of topical melatonin cosmetic hair solution (Asatex®) in the treatment of hair loss (telogen) and in the stimulation of hair re-growth (anagen)

MEL-COS-AS05

(Protocol Code: ASA-B-01)

ASATEX®
Cosmetic Melatonin Hair Product in Monodoses

Confidential

ASATONA AG
Grienbachstrasse 17
CH-6300 Zug / Switzerland

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Introduction

Going bald and losing hair has been a problem for men and women since the dawn of time. Hair performs no vital function relative to the medical well being of humans. Yet the psycho-social implications can never be underestimated. Scalp hair can be the crowning glory for the femininity of women and a potent symbol of masculinity and security in men. Hair loss is an extremely common disorder affecting both men and women. The incidence is generally considered to be greater in males than females, although some evidence suggests that the apparent differences in incidence may be a reflection of different expression in males and females. This genetically determined disorder is progressive through the gradual conversion of terminal hairs into indeterminate hairs and finally to vellus hairs. Patients have a reduction in the terminal-to-vellus hair ratio, normally at least 2:1. Following miniaturization of the follicles, fibrous tracts remain. Normally, we lose between 50 and 100 hairs per day as a result of our normal hair cycle. However, when this cycle is abnormal and hair loss is no longer falling out in a natural, random pattern, it can develop a temporary or ongoing disease state. Unfortunately, certain individuals are predisposed to the types of hair loss which progress into this disease state. Physical harm to the scalp, certain medications, excessive use of styling products, surgical procedures, severe infections, eating disorders, and certain physiological conditions, such as thyroid disease, are other causes of temporary or permanent hair loss. Patients with this disorder usually have a typical distribution of hair loss.

This is an extremely common disorder that affects roughly 50% of men and perhaps as many women older than 40 years. As many as 13% of premenopausal women reportedly have some evidence of androgenic alopecia. However, the incidence increases greatly in women following menopause, and, it may affect 75% of women older than 65 years.
The incidence and severity of hair loss tend to be highest in white men, second highest in Asian and African Americans, and lowest in Native Americans and Eskimos.

Almost all patients have an onset prior to age 40 years, although many of patients (both male and female) show evidence of the disorders by age 30 years. The onset is gradual. Men present with gradual thinning in the temporal areas, producing a reshaping of the anterior part of the hairline. For the most part, the evolution of baldness progresses according to the Hamilton classification of frontal and vertex thinning. Women usually present with diffuse thinning on the crown. Bitemporal recession does occur in women but usually to a lesser degree than in men. In general, women maintain a frontal hairline.

In both males and females with hair loss, the transition from large, thick, pigmented terminal hairs and finally to short, wispy, non pigmented vellus hairs in the involved areas is gradual. As the disorder progresses, the anagen phase shortens with the telogen phase remaining constant. As a result, more hairs are in the telogen phase, and the patient may notice an increase in hair shedding. The end result can be an area of total denudation. This area varies from patient to patient and is usually most marked at vertex. Women with hair loss generally lose hair diffusely over the crown.

This produces a gradual thinning of the hair rather than an area of marked baldness. The part is widest anteriorly. The frontal hairline is often preserved in women with this disorder, whereas men note a gradual recession of the frontal hairline early in the process.

The aim of treatment of hair loss is to increase scalp coverage or to retard the progression of hair thinning, or both. Agents used to treat hair loss may be non-specific biologic response modifiers that enlarge suboptimal hair follicles regardless of the underlying pathophysiology, androgen blockers or androgen receptor inhibitors to specifically block the binding and transport of androgens to the cell nucleus.

Asatona AG has developed the new melatonin cosmetic hair solution (Asatex®) which has an effect on extrinsic factors in reducing the oxydative stress thanks to its strong radical scavenging properties. It also acts on intrinsic factors by its interaction with the melatonin receptors in the scalp and the hair follicle. On the basis of the data existing in the literature, this study has been carried out to evaluate the role of melatonin in the treatment of patients affected by early stages of androgenic alopecia. The study has been designed to assess clinical efficacy and safety of melatonin cosmetic hair solution.

Materials and methods

Study design
This open-label, non comparative, multicenter study has been conducted in 200 Centres. All subjects signed an informed consent form before the start of the trial.

Patient selection

One thousand and nine hundred patients of both sexes aged between 18 to 40 years have been enrolled in this clinical study.
Inclusion criteria stipulated progressive hair loss with androgenic alopecia in males on stage I and II on the Hamilton scale and in females on stage I and II on the Ludwig scale. Subjects affected by severe systemic pathologies or previously treated with systemic finasteride or minoxidil or subjects that have been treated topically with specific non pharmacological products by 15 days from starting of the study, or females who have a positive pregnancy test within 24 hours prior to study entry, or are otherwise known to be pregnant, or are currently breastfeeding, or subjects with known allergy to some components of the product, have not been allowed to be treated with the topical product.

Study product
The composition of melatonin cosmetic hair solution is reported in the following table:

Melatonin cosmetic hair solution (ASATEX*)
Composition

Formulation No. 157/001/012

Ingredient	INCI declaration	% [W/W]
Water, demin	Aqua	68.4367
Ucare Polymer JR 125	Polyquaternium	0.12
Citric Acid	Citric Acid	0.08
Polyglykol 400	**PEG-8**	0.50
Ginkgo Biloba DryExtract	Ginkgo Biloba	0.05
Edeta BD	Disodium EDTA	0.03
Fragrance "Outfit" 242942	Parfum	0.12
Menthol-L Komp. (620009)	Menthol	0.10
Camphor (+) refined, Art. 102166	Camphor	0.05
Cremophor RH 40	PEG-40 Hydrogenated Castor Oil	0.50
Ethanol 96% Sorte 611	Alcohol denat.	30.00
Rona Care Biotin Art. 130 220	Biotin Melatonin	0.01
Melatonin		0.0033
Sodium Hydroxide (10 % aq.) (from pellets, Art. 106482)	Sodium Hydroxide	(ad pH 3,8)
		100.00

Treatment

Patients who met the inclusion criteria were eligible for the topical treatment with melatonin cosmetic hair solution. A daily topical application of the product to the scalp skin for 90 days have been recommended. Patients washed the scalp before the application of the topical hair solution or the following morning. It was recommended to wash the scalp skin only once daily. The product has been applied on dry hairs. The all topical hair solution has been supplied at no charge to the participants.
At baseline visit all patients were given instructions regarding the general conduct of the trial and the proper use of the trial product. Every night all patients have been requested to apply the dose of one vial of product to the scalp skin, with a light massage.

Efficacy assessment

Efficacy has been assessed according to the following objective and subjective variables:

- Physician's evaluation:

  The evaluation included the Pull test, seborrhea and seborrhoic dermatitis assessed at baseline visit and after 30 and 90 days and the efficacy of the treatment assessed at 30 and 90 days.
  The assessments have been categorized as follows:

  Pull test (positive/negative)
  + = slight
  ++ = moderate
  +++ = severe
  0 = negative

  Seborrhea
  + = slight
  ++ = moderate
  +++ = severe
  0 = absent

  Seborrhoic dermatitis
  presence
  absence

  Efficacy
  1 = increased hair loss
  2 = stable situation
  3 = slight improvement with a reduction of hair loss
  4 = moderate improvement with discontinuance of hair loss
  5 = hair growth

- Subject's evaluation:

All subjects have been asked the evaluation of the effects of treatment. The hair loss assessment has been done at baseline visit and after 30 and 90 days of treatment. The tolerability of the topical hair solution expressed by the manifestation of any discomfort or symptom of the skin or other irritation and the degree of the cosmetic satisfaction with the hair growth and the appearance of hair in the affected area have been done after 30, 90 days of treatment. The assessments have been categorized according to the following scales:

Hair loss
1= severe
2= slight
3= no hair loss

Tolerability
1 = poor tolerability
2 = tolerated
3 = well tolerated

Cosmetic satisfaction
1 = not satisfied
2 = moderately satisfied
3 = satisfied

- Physician's and Patient's evaluations

Clinical response in regard to the hair loss in comparison with other previously used products have been done at the end of treatment.

The assessments have been categorized as follows:
1= worse
2= equal
3= better

Safety assessment

All patients who received the study product have been carefully monitored for adverse events and were included in the safety evaluation. Safety has been evaluated on the basis of adverse events.

Statistical analysis

Outcomes were calculated according to the total number of evaluable patients.
Objective and subjective clinical variables have been assessed at baseline and after 30 and 90 days of treatment. Comparability of outcomes between baseline and end of treatment visit has been performed. Scores of Pull test, seborrhoea, hair loss, efficacy, tolerability and cosmetic satisfaction have been analyzed by means of Paired Student's t-test. P-values less than or equal to 0.05 have been considered statistically significant.

Results

❖ Patient population

One thousand and nine hundred patients have been recruited in 200 Centres. Patients who met the inclusion criteria have been admitted in this clinical study. The mean (± SD) age of the patients was 35.3 (± 6.9) years. Of the total evaluable patients, 901 were males (47.6%) and 990 were females (52.4%) (Fig. 1).

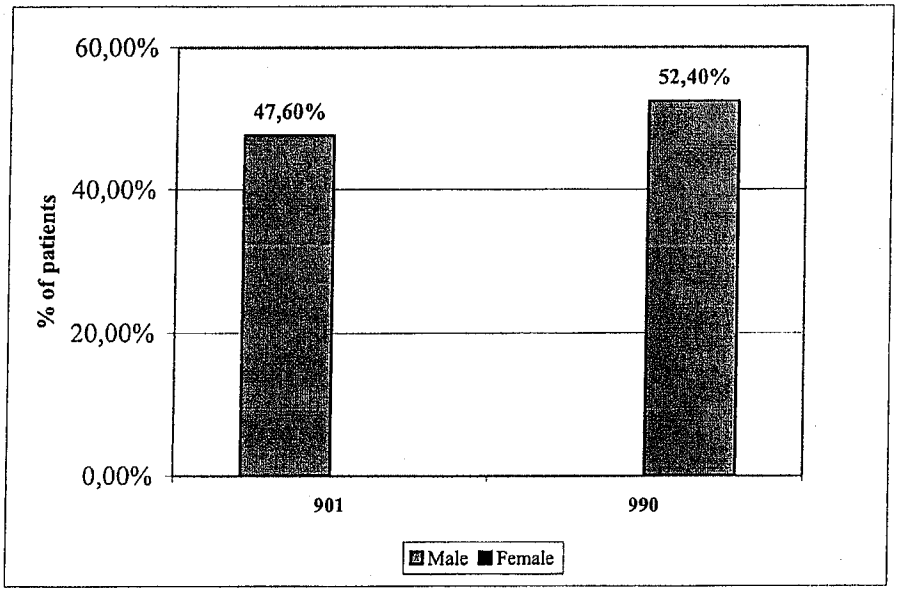

Figure 1 - Demographics : number and % of patients

Four hundred and fifty two males (50.6%) have been affected by androgenetic alopecia on stage I and 442 males (49.4%) on stage II of the Hamilton scale (Fig. 2). Of the 990 females, 626 (63.9%) have been classified on stage I and 354 females (36.1%) on the stage II of Ludvig scale (Fig. 3).
The product has been applied daily for 90 days and the patient evaluation has been performed after 30 and 90 days of treatment.

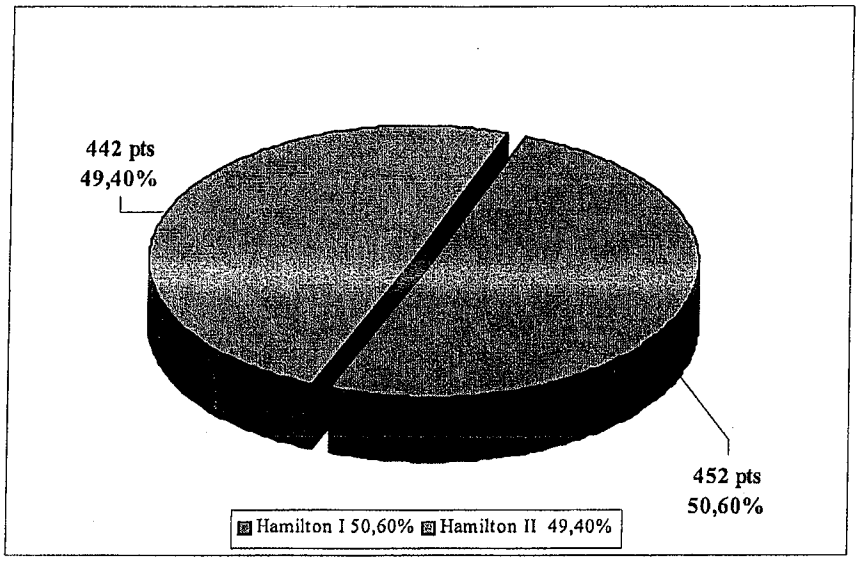

Figure 2 - Hamilton Scale: number and % of Male

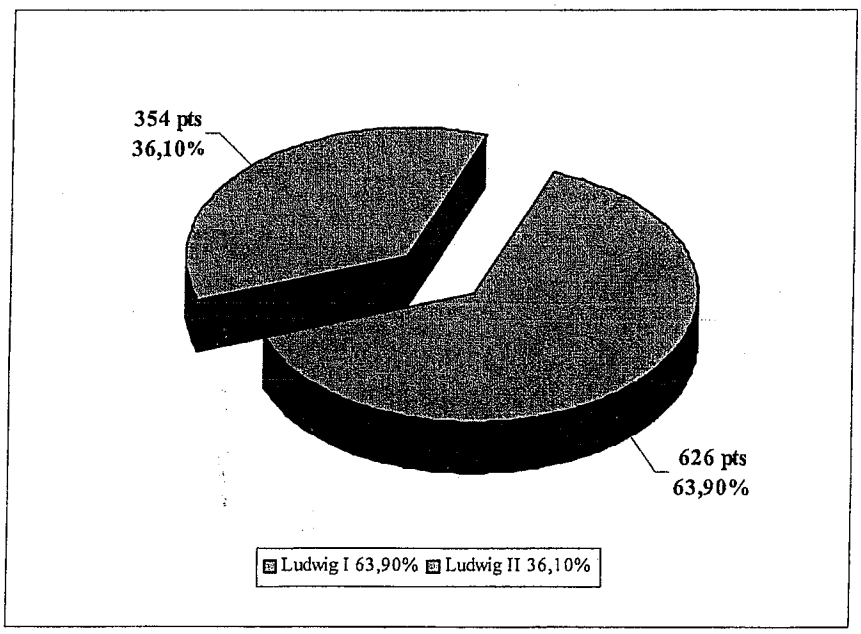

Figure 3 - Ludwig Scale: number and % of Female

❖ **Efficacy**

Pull test

For each participant, the initial hair loss and the evaluation of Pull test, the severity of seborrhea and the presence of seborrhoic dermatitis served as baseline to calculate the change following the treatment.
Clinical pattern observed during the study has been improved in most treated patients. These changes have been time-dependent and statistically significant.

Improvement of the Pull test performed by the physician has been noticed at one and three months. At baseline visit the scores have been slight in 26.2%, moderate in 42.8%, severe in 18.8% and absent in 12.2% of patients. After three months of treatment decreases of moderate and severe gravity in 7.4% and 0.4% of patients respectively and increase of absence of gravity in 61.5% of patients have been observed. This improvement has been time-dependent and statistically significant ($p < 0.001$) at 30 days and at the end of treatment (Fig. 4).

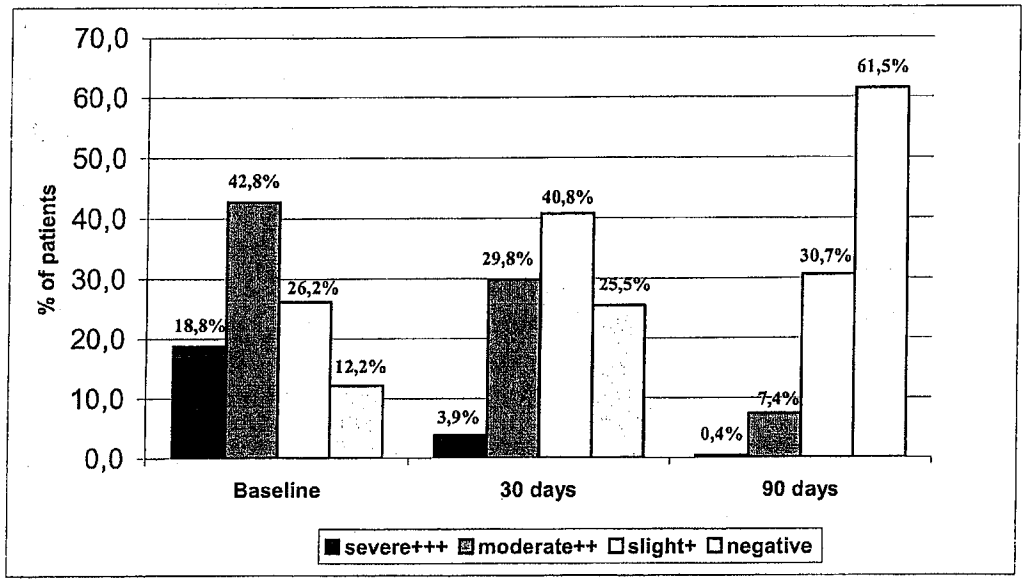

Figure 4 - Pull test T30 and T90 - % of patients; p<0.001

Seborrhea

More than 65% of patients manifested seborrhea at baseline visit. In fact this disease has been slight in 31.8%, moderate in 28.0% and severe in 7.7% of patients. Absence of seborrhea has been observed in 32.5% of cases. Improvement of seborrhea has been registered after one and three months of treatment and the differences have been statistically significant ($p < 0.001$). Decrease of slight (27.0%), moderate (4.9%) and severe (0.5%) gravity and increase of absence of the disease (67.6%) have been observed after 90 days (Fig. 5).

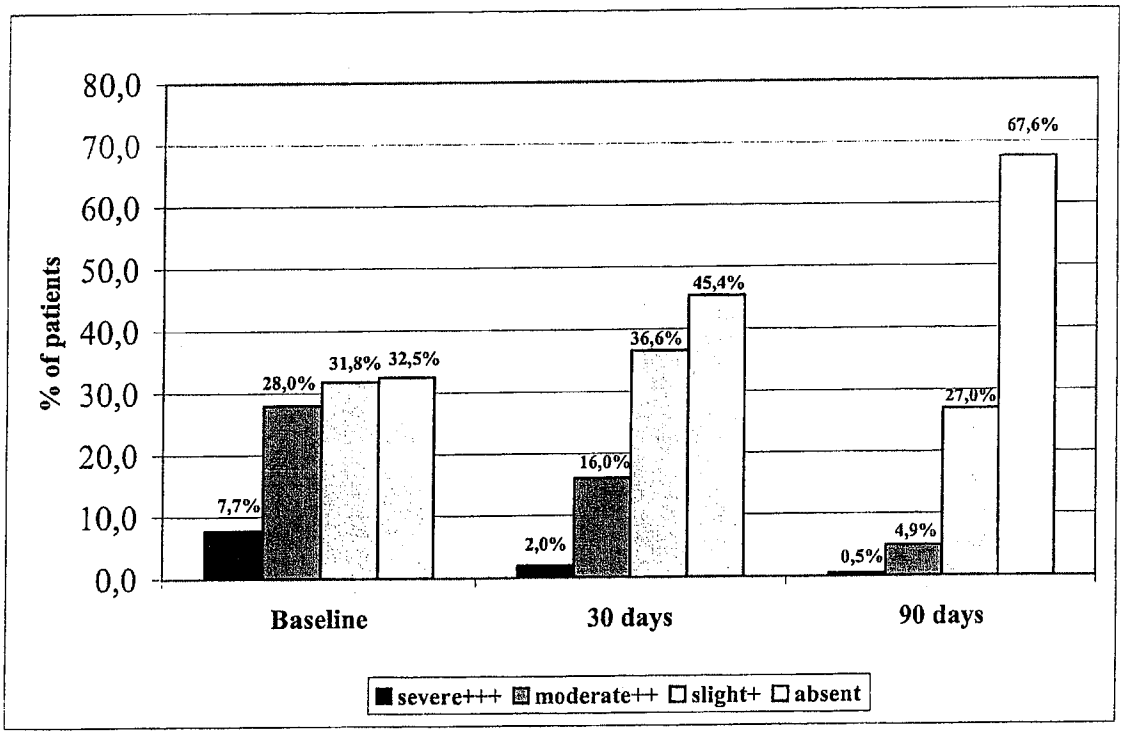

Figure 5 - Seborrhea T30 and T90 - % of patients; $p<0.001$

Seborrhoic Dermatitis

Moreover 34.5% of patients evidenced seborrhoic dermatitis at baseline visit and the disease disappeared in 77.6% and 90.1% of patients at one and three months of treatment respectively (Fig. 6).

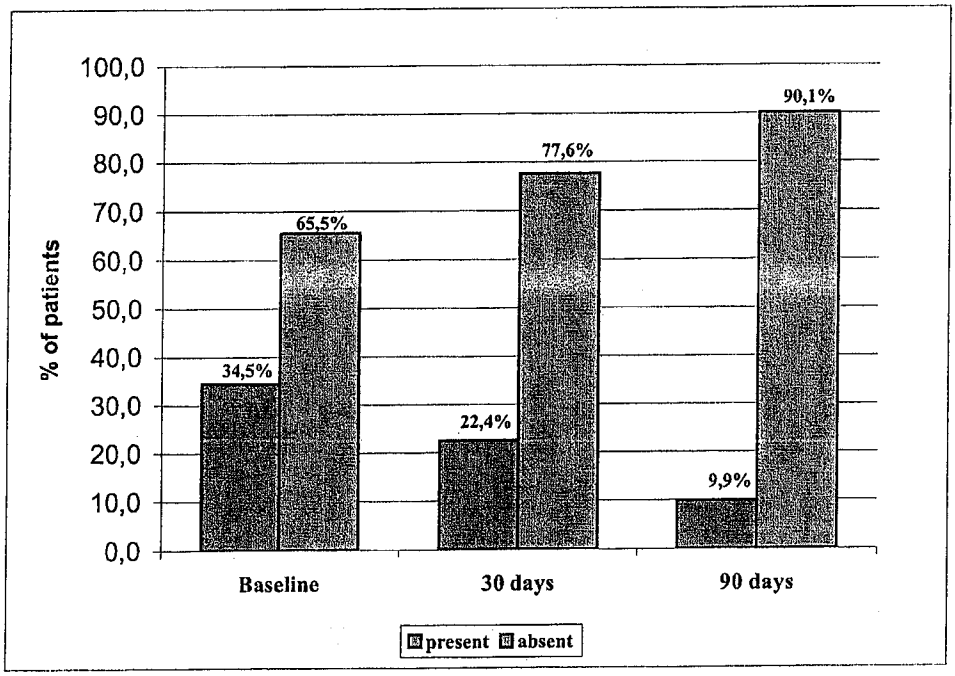

Figure 6 - Seborrhoic Dermatitis T30 and T90 - % of patients

Efficacy assessment by the physician

The efficacy of treatment has been confirmed by the physician also by the assessment of hair appearance. At the end of treatment slight or moderate improvements have been registered in 25.2% and 41.2% of patients respectively. The improvement has been shown also at 30 days.
The efficacy of treatment has been confirmed by the hair re-growth that has been observed in 4.5% and 22.5% of patients after one and three months respectively. Hair appearance has been equal to baseline in 30.7% of patients after one month and in 8.6% of cases after three months of treatment and worsened only in 5.4% and 2.5% of cases at 30 and 90 days respectively. The improvement of efficacy has been statistically significant ($p < 0.001$) (Fig. 7).

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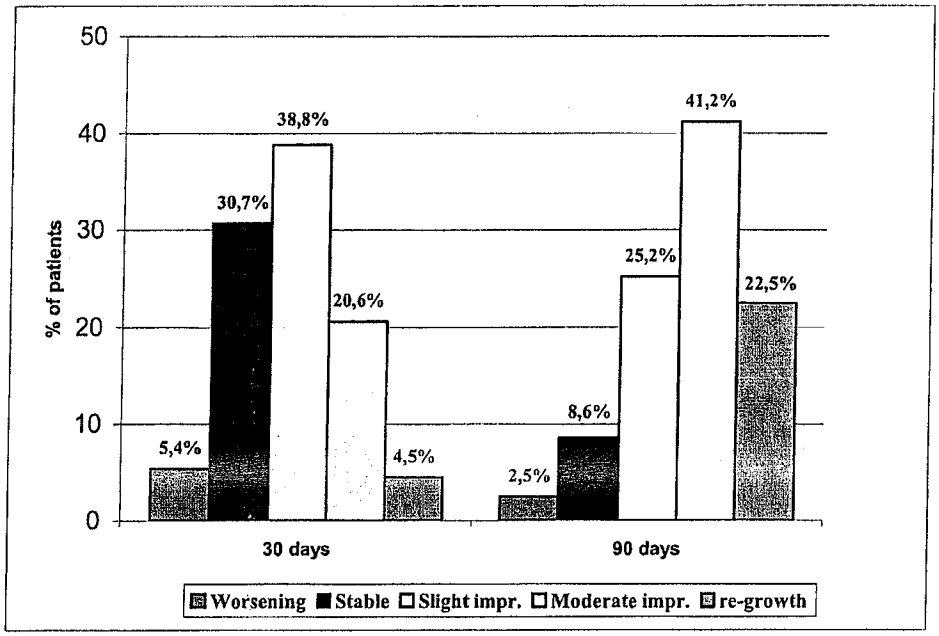

Figure 7 - Efficacy-Physician's Assessment T30 and T90 - % of patients; p<0.001

Subjects evaluation

The hair loss evaluated by the patients at baseline visit has been slight and severe in 46.3% and 25.0% of cases respectively. No hair loss at baseline visit has been observed in 28.7% of patients. After three months of treatment the decrease of patients with slight hair loss (30.4%) and substantially the same number of cases (29.6%) with severe gravity have been registerd. Absence of hair loss has been observed in 40.0% of patients at the end of treatment. The improvement of hair loss has been statistically significant (p< 0.001) (Fig.8).

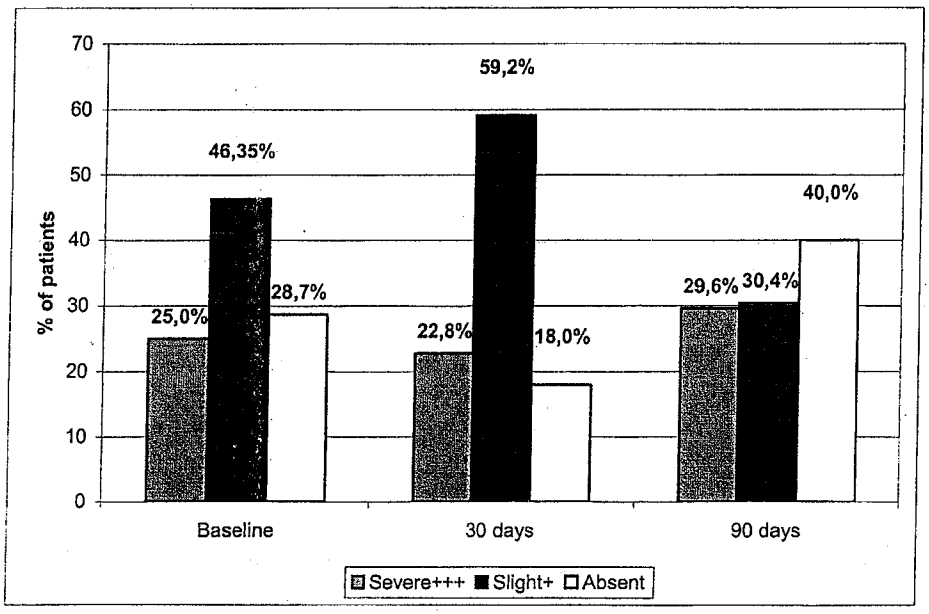

Figure 8: Hair loss T30 and T90 – percentage of patients; p< 0.001

Cosmetic satisfaction

Subjective cosmetic satisfaction by the patient revealed good level of satisfaction already after one month of treatment in most patients. In fact 37.0% of patients have been moderately satisfied and 58.0% have been satisfied of the treatment. This positive evaluation has been confirmed at 90 days. After three months of treatment 23.3% of patients have been moderately satisfied and 74.4% were satisfied and only 2.3% expressed dissatisfaction. These changes have been statistically significant ($p < 0.001$) (Fig. 9).

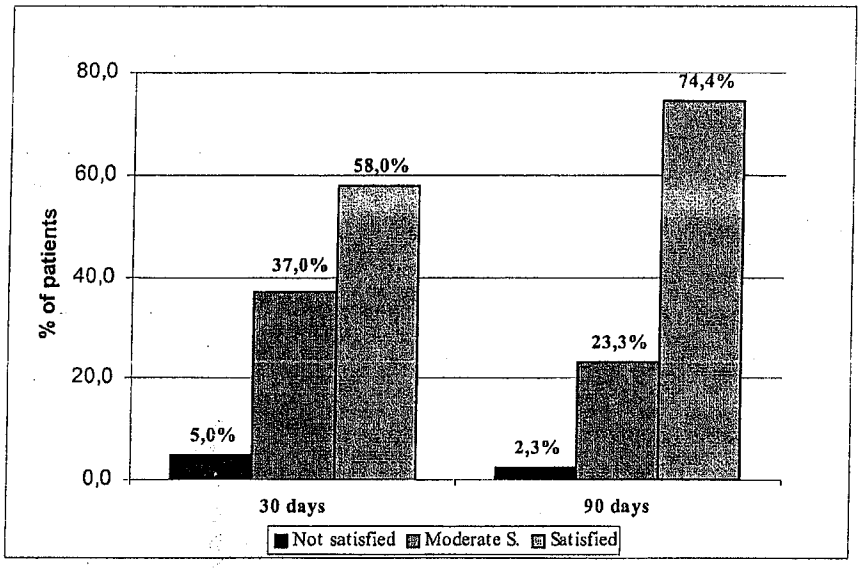

Figure 9 - Patients' Cosmetic Satisfaction T30 and T90 - % of patients; p<0.001

Tolerability

The melatonin cosmetic hair solution proved to be well tolerated in the majority of patients.
The evaluation performed by the patients evidenced that the product has been tolerated or well tolerated in 14.3% and 82.7% of patients respectively at three month treatment.

The good tolerability has been observed also after one month of treatment. Only 2.8% of patients evidenced low tolerability at the end of treatment. The differences of tolerability has been statistically significant ($p < 0.001$) (Fig. 10).

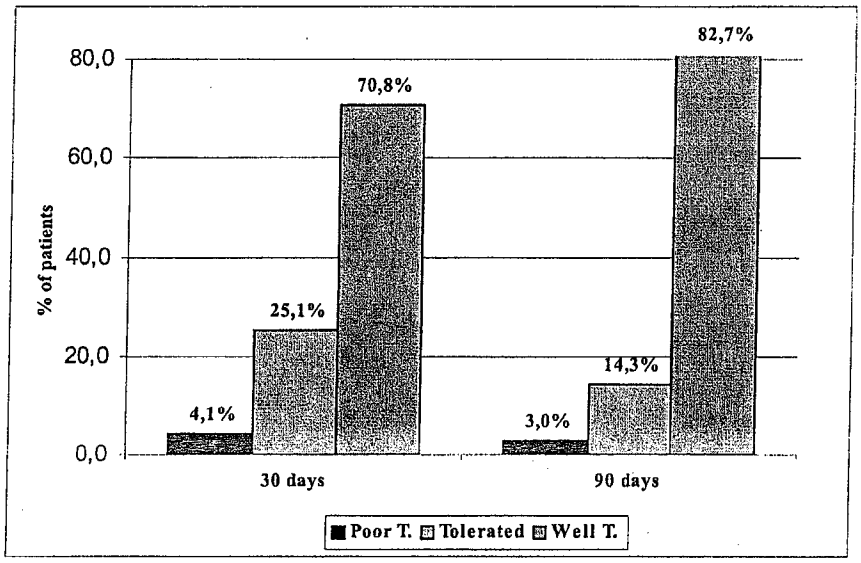

Figure 10 - Tolerability - Patients' Assessment T30 and T90 - % of patients; p<0.001

Similar evaluation has been expressed also by the physician. The tolerability assessed by the physician showed that the topical hair solution has been tolerated or well tolerated in 10.0% and 88.0% of patients respectively after three months of treatment and only in 2.0% of cases low tolerability has been registered. Similar results have been observed also after one month of treatment. These changes have been statistically significant (p< 0.001) (Fig. 11).

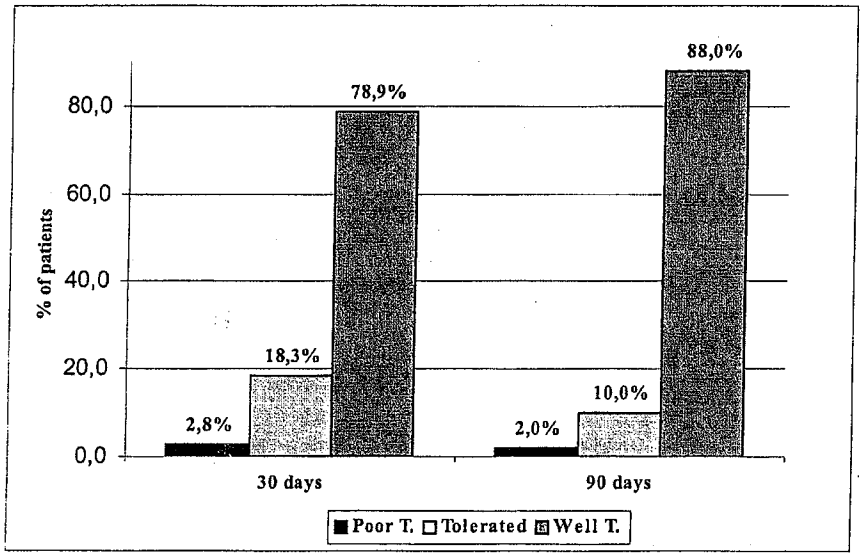

Figure 11 - Tolerability - Physicians' Assessment T30 and T90 - % of patients; p<0.001

Global evaluation

The efficacy of the product has been assessed also by the physician's and patient's global evaluation concerning the hair loss in comparison with others products previously used.

Melatonin cosmetic hair solution proved to have more efficacy than other products previously used for the treatment of hair loss. In fact both physician's and patient's global evaluations have been better than other products in 85.3% and 80.8% of patients respectively, while they have been equal in 14.0% and 18.2% of cases respectively. In the other patients the global evaluation worsened (Fig. 12).

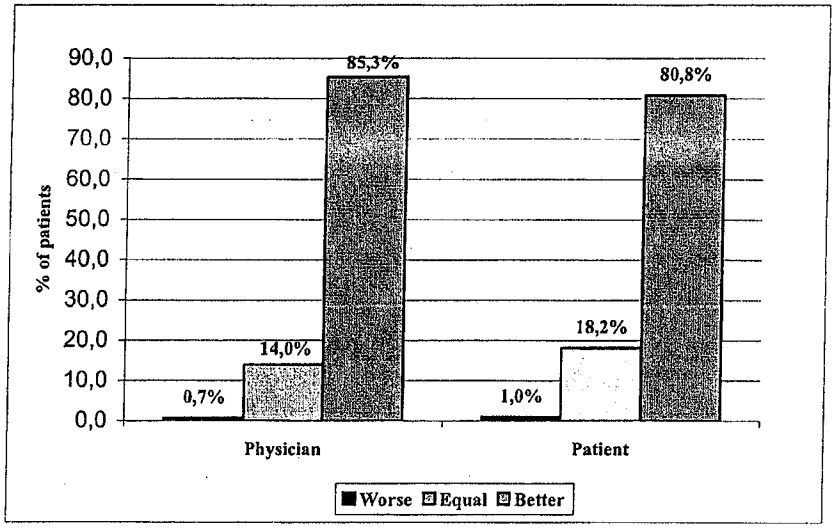

Figure 12 - Global Evaluation T 90

❖ **Safety**

Melatonin cosmetic hair solution has been very safe. Side effects following the application of the product on the scalp have been registered in only 1.7% and 0.9% of patients after one and three months of treatment respectively.
The level of compliance has been very high in all subjects and the product has been applied daily for three months.

Discussion

Although hair loss is a mainstream condition, most people fail to realize that permanent hair loss is a disease. Person with male-pattern or female-pattern baldness may be topically treated with hair loss products which may promote hair growth. Recent studies show the effectiveness of topical melatonin, a natural ingredient, for women with hair loss. This product has been shown to restore the appearance of existing hair, while decreasing the psychosocial impact of hair loss.

On the base of these results a multicentric study has been carried out with melatonin topical solution on a large number of patients affected by early stages of alopecia both in males and females. The product has been applied on the scalp of patients for three months and the beneficial effect of the treatment has been defined as increase of density of hairs and reduction of hair loss.

The results of this study carried out in a large number of patients (1900) showed the efficacy and safety of melatonin cosmetic hair solution in the treatment early stages of hair loss in males and females.

The efficacy of the product has been evaluated by response to Pull test, grade of hair loss intensity and hair appearance. These objective parameters evidenced the activity of melatonin hair solution at one and three months of treatment. Decrease of gravity of Pull test has been statistically significant ($p< 0.001$) and in more than 60.0% of participants the test has been negative at 90 days. Moreover most patients revealed the statistically significant ($p< 0.001$) decrease of hair loss and 39.9% of cases referred absence of hair loss. The product improved the seborrhea which was present in about 67.0% of patients at baseline visit. This disease disappeared in 45.5% and 67.6% of patients after 30 and 90 days of treatment respectively and in the other cases the decrease of intensity has been statistically significant ($p< 0.001$). Moreover reduction of number of patients affected by seborrhoic dermatitis has been registered at one month and more evident at 90 days of treatment.

In the assessment of efficacy of cosmetic treatment, satisfaction of the subject with the results of the treatment is of great importance. For men and women who care about their appearance, even reduction of hair loss or stable situation are considered an improvement. Most patients have been satisfied of the cosmetic treatment with a positive effect on their hair at one and three months. This evaluation is in agreement with the physician's assessment of efficacy of the product on the hair loss. In fact the hair appearance improved in more than 60.0% of patients both at 30 and 90 days and in 22.5% of cases hair re-growth has been observed after three months of treatment and the differences have been statistically significant ($p< 0.001$).

The product, is effective and is also very well tolerated. Both physician's and patient's evaluations referred good tolerability of melatonin hair solution in most patients at 30 and 90 days and the differences have been statistically significant ($p< 0.001$). Moreover the product proved to be very safe when is applied on the scalp and no side effects have been noticed in most patients.

The efficacy and safety of melatonin hair solution have been confirmed also by the physician's and patient's global evaluations which comprise changes in hair loss, tolerability and safety of the product in comparison with other products previously used. In most patients treated for three months both the evaluations have been better or equal than other products previously used.

In conclusion the results obtained in this study suggest that the melatonin cosmetic hair solution (Asatex®) appeared to be beneficial for the treatment of male and female patients affected by early stages of androgenic alopecia. The application of the product on the scalp generated a protective effect against oxidative stress, stimulated the hair follicles and induced revitalization of the hair as indicated by the cessation of hair loss in most subjects and increased growth of new hair in some cases.

References

Hamilton, J.B. (1951). Patterned loss of hair in man: types and incidence. Annal NY Acad Sci 53, 708-728.

Norwood, A.G. (1975). Male pattern baldness: Classification and incidence. Southern Medical Journal, 68, 1359-1365.

Hoffmann R: TrichoScan: a novel tool for the analysis of hair growth in vivo. J. Invest. Dermatol. Symp. Proc. 2003 Jun; 8 (1): 109-15

Hoffmann R: TrichoScan: combining epiluminescence microscopy with digital image analysis for the measurement of hair growth in vivo. European-Journal-of Dermatology. Jul-Aug 2001; 4 (11): 362-368

Cash, T.F. (1992). The psychological effects of androgenic alopecia in men. Journal of the American Academy of Dermatology, (26), 926-931

Setty, L.R. (1970). Hair patterns of scalp of white and Negro males. Am J Phys Anthropol 33, 49-55.

Courtois, M. et al. (1994). Hair cycle and alopecia. Skin Pharmacol 7, 84-89.

Kligman, A. (1959). The human hair cycle. J Invest Dermatol 33, 307-316.

Oliver, R. and Jahoda, C. (1989). The dermal papilla and the maintenance of hair growth. In The Biology of Wool and Hair (Rogers, G. et al, eds), pp. 51-67, Chapman and Hall, London, UK

Obana, N. and Uno, H. (1996). Dermal papilla cells in macaque alopecia trigger a testosterone-dependant inhibition of follicular cell proliferation. In Hair research in the next millennium (van Neste, D. and Randall, V, eds), pp. 307-310, Elsevier, UK

Randall, V.A. (1996). The use of dermal papilla cells in studies of normal and abnormal hair follicle biology. Dermatol Clin 14, 585-594.

Andrzej Slominski, Jacobo Wortsman & Desmond J. Tobin (2005), FASEB Journal 19, 176-194.

Trueb, R.M.(2003). Is androgenetic alopecia a photoaggravated dermatosis?
Dermatology 207, no. 4:343-348.